

# Exhibit 1

**LETTER OF REQUEST**

(Convention of 18 Mar 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters)

1.	Sender	Judge Robert W. Schroeder III United States District Court, Eastern District of Texas Sam B. Hall, Jr. Federal Building and United States Courthouse 100 East Houston Street Marshall, TX 75670 USA
2.	Central Authority of the Requested State	The Senior Master For the attention of the Foreign Process Section Room E16 Royal Courts of Justice Strand London WC2A 2LL
3.	Person to whom the executed request is to be returned	Samuel Lockner Carlson Caspers 225 S. Sixth St., Suite 4200 Minneapolis, MN 55402 USA +1 (612) 436-9644 slockner@carlsoncaspers.com sun-sezaby@carlsoncaspers.com
4.	Specification of the date by which the requesting authority requires receipt of the response to the Letter of Request	
	Date	February 1, 2025
	Reason for urgency	The discovery period in this action, that is, the period in which the parties may obtain evidence for use at trial from each other or from non-parties, ends on August 8, 2025 under the current case schedule.

In conformity with Article 3 of the Convention, the undersigned applicant has the honor to submit the following request:

5. a	Requesting authority (Art. 3(a))	Judge Robert W. Schroeder III United States District Court, Eastern District of Texas Sam B. Hall, Jr. Federal Building and United States Courthouse 100 East Houston Street Marshall, TX 75670 USA
------	----------------------------------	---

b	To the Competent Authority of (Art. 3(a))	The United Kingdom
c	Names of the case and any identifying number	<i>Nivagen, Inc. v. Sun Pharmaceuticals Industries, Inc.</i> , No. 2:24-cv-36-RWS-RSP (U.S. District Court for the Eastern District of Texas)

6.	Names and addresses of the parties and their representatives (including representatives in the Requested State) (Art. 3(b))	
a	Plaintiffs	Nivagen, Inc. 3050 Fite Circle, Suite 100 Sacramento, CA 95827 USA
	Representatives	Shashank Upadhye Yixin Tang Brent Batzer Upadhye Tang LLP 109 Symonds Dr. #174 Hinsdale, IL 60522 Phone: +1-312-598-2612 Email: shashank@ipfdalaw.com yixin@ipfdalaw.com brent@ipfdalaw.com  Melissa R. Smith Gilliam & Smith, LLP 303 South Washington Avenue Marshall, Texas 75670 Phone: +1-903-934-8450 Email: melissa@gillamsmithlaw.com
b	Defendants	Sun Pharmaceutical Industries, Inc. 2 Independence Way Princeton, NJ 08540 USA
	Representatives	J. Derek Vandenburg Samuel T. Lockner Seung Sub Kim Justin T. Oakland Carlson, Caspers, Vandenburg & Linquist, P.A. 225 South Sixth Street, Suite 4200 Minneapolis, MN 55402

	<p>Phone: +1-612-436-9600 Email: dvandenburgh@carlsoncaspers.com slockner@carlsoncaspers.com ekim@carlsoncaspers.com joakland@carlsoncaspers.com sun-sezaby@carlsoncaspers.com</p> <p>Eric H. Findlay Findlay Craft, P.C. 7270 Crosswater Avenue, Suite B Tyler, TX 75703 Phone: +1-903-534-1100 Email: efindlay@findlaycraft.com</p>
--	---

7. a	Nature of the proceedings	Action for damages alleging patent infringement.
b	Summary of the case	Nivagen, Inc. alleges that it is the owner of US Patent Nos. 11,406,598 (“the ’598 Patent”) and 11,878,076 (“the ’076 Patent”). The patents’ subject matter relates to a lyophilized phenobarbital sodium injection and methods of manufacturing phenobarbital sodium injections involving lyophilization. Phenobarbital sodium is a drug commonly used in the treatment of neonatal seizures. Nivagen alleges that Sun Pharmaceutical Industries, Inc., has infringed the patents by manufacturing, offering for sale, and selling Sun’s “Sezaby” phenobarbital sodium drug product, which was approved by the US Food and Drug Administration on November 17, 2022.
c	Summary of defense and counterclaim	Sun denies that it has infringed Nivagen’s patents and claims that the asserted patents are invalid because in light of the prior art, they are obvious or anticipated by one of ordinary skill and training in the art, and because of lack of enablement, lack of written description, and indefiniteness.
d	Other necessary information or documents	The Court has entered a protective order in this case, which allows for the production of documents by parties or by third parties to be subject to protections against the disclosure of confidential documents, or the information they contain, and for the protection of testimony designated as confidential from disclosure. The protective order is attached as Attachment A. Under the protective order, Pharmanovia may designate documents as confidential, and the Court will apply the protective order with respect to Pharmanovia’s documents just as it would to documents produced by US parties.

		<p>The Court is aware of the United Kingdom's declaration under Article 23 of the Evidence Convention. It appears likely to the Court that the documents requested in Item 11 are likely to be in the possession, custody, or power of Pharmanovia. In 2023, Pharmanovia acquired the central nervous system portfolio from French pharmaceutical company Sanofi which included GARDENAL®. In order for a drug to be marketed in France, a manufacturer must obtain a Marketing Authorization from the Ministry of Health of France. This process requires the manufacturer to submit technical documentation for approval. When Sanofi sought Marketing Authorization for GARDENAL® it submitted documents likely responsive to those requested in Item 11, and those documents are likely now in Pharmanovia's possession, custody, or power.</p> <p>The Court is also satisfied that the documents have been identified with the particularity that is possible in the circumstances of the case. Pharmanovia may use names for documents different than the names given in Item 11 (for example, it may use a particular term or terms in place of "technical documents that demonstrate the manufacturing process"). But the Court is satisfied that the requests have a definite meaning that should be intelligible to the relevant Pharmanovia personnel.</p>

8. a	Evidence to be obtained or other judicial act to be performed (Art. 3(d))	The production of documents identified in Item 11.
b	Purpose of the evidence or judicial act sought.	<p>Sun has represented to the Court that the documentary evidence sought is material to its defense, because it will show that the asserted patents are invalid based on the prior art. The Court has determined, based on the parties' submissions, that Pharmanovia, the UK entity from which Sun seeks discovery, is likely to possess the documents sought. In particular, Pharmanovia sells GARDENAL®, a phenobarbital drug product. Certain inherent properties of GARDENAL® are not explicitly disclosed in the public domain (for example, whether it is amorphous, or the levels of certain impurities). Pharmanovia acquired a CNS drug portfolio from Sanofi S.A. in 2023, and the Court has found there is reason to believe that the patent portfolio includes information regarding the development, drug approval process, and market authorization for GARDENAL®,</p>

		which is likely to include information about those inherent properties. This information may be included in documents describing the manufacturing processes, stability, impurities, and other drug product characteristics for GARDENAL®.
--	--	--

9.	Identity and address of persons to be examined (Art. 3(e))	Pharmanovia Sovereign House Miles Gray Road Basildon, Essex SS14 3FR
10.	Questions to be put to the persons to be examined, or statements of the subject matter about which they are to be examined (Art. 3(f))	Not applicable.
11.	Documents or other property to be inspected (Art. 3(g))	<ol style="list-style-type: none"><li>1. The technical documents that demonstrate the manufacturing process of GARDENAL® prior to September 20, 2019. These documents are expected to include a list of excipients or carriers, to disclose whether drug product undergoes the process of lyophilization, and if so, the process and parameters of lyophilization used.</li><li>2. The documents submitted to the Ministry of Health in connection with the application for Marketing Authorization that evidence the stability testing of GARDENAL® over time (e.g., over GARDENAL® shelf life), prior to September 20, 2019.</li><li>3. The documents submitted to the Ministry of Health in connection with the application for Marketing Authorization that evidence the impurities and degradants present in GARDENAL®, including the content and qualification specifically of 2-ethyl-2-phenylmalonamid (2EPMM), alpha-phenylbutyrylguanidine (PBG), and/or phenylethylacetylurea (PEAU), prior to September 20, 2019.</li><li>4. The documents submitted to the Ministry of Health in connection with the application for Marketing Authorization that evidence the structural characterization of phenobarbital active pharmaceutical ingredient (API) and the final drug product of GARDENAL® prior to September 20, 2019, including specifically whether the API or final product is amorphous (e.g., x-ray diffractograms).</li></ol>

		5. The documents submitted to the Ministry of Health in connection with the application for Marketing Authorization that evidence the purity of GARDENAL®, including assays and moisture content of phenobarbital active pharmaceutical ingredient.
12.	Any requirement that the evidence be given on oath or affirmation and any special form to be used (Art. 3(h))	Not applicable.
13.	Special methods or procedures to be followed (Arts 3(i) and 9)	Because this letter seeks evidence for admission at trial, and because the US law of evidence requires that evidence must be authenticated before it can be admitted at trial and requires evidence of certain facts before business records containing hearsay can be admitted at trial, the Court requests that the UK authorities require Pharmanova, by an appropriate corporate representative, execute the declaration attached to this letter as Attachment B, which is in a form ordinarily used in the United States to authenticate business records for use at trial without the need for a witness to testify concerning the documents. The declaration is drafted to meet the requirements of Rule 803(6) of the Federal Rules of Evidence, which defines the business records exception to the hearsay rule, and Rule 902(12) of the Federal Rules of Evidence, which defines the requirements for a declaration that can serve to authenticate foreign business records. In order to meet the requirements of Rule 902(12), the Court respectfully requests that the declaration be executed in a manner that would, if false, subject the maker to a criminal penalty under UK law (for example, an affidavit sworn before a notary).
14.	Request for notification of the time and place for the execution of the Request and identity and address of any person to be notified (Art. 7)	The Court requests that the party representatives listed in Item 6 be notified in advance, by post and email, of the time and place for execution of the Request.

15.	Request for attendance or participation of judicial personnel of the requesting authority at the execution of the Letter of Request (Art. 8)	Not applicable.
16.	Specification of privilege or duty to refuse to give evidence under the law of the Requesting State (Art. 11(b))	Under the law of the United States a witness can refuse to produce documents if the documents would disclose communications with a lawyer made for the purpose of seeking or receiving legal advice. A natural person (but not a corporation or other business entity) also has a privilege against self-incrimination. Various other privileges exist, none of which have any likely application in this case.
17.	The fees and costs incurred which are reimbursable under the second paragraph of Article 14 or under Article 26 of the Convention will be borne by:	The defendant. The Court respectfully requests advance notice if the reimbursable costs are expected to exceed \$5,000.

Date of request	
Signature and seal of the Requesting Authority	

# Attachment A

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

NIVAGEN, INC.

Plaintiff

v.

SUN PHARMACEUTICALS INDUSTRIES,  
INC..

Defendant.

Case No.: 2:24-cv-00036-RWS-RSP

**PROTECTIVE ORDER**

WHEREAS, Plaintiff Nivagen and Defendant Sun Pharmaceuticals Industries, Inc., hereafter referred to as "the Parties," believe that certain information that is or will be encompassed by discovery demands by the Parties involves the production or disclosure of trade secrets, confidential business information, or other proprietary information;

WHEREAS, the Parties seek a protective order limiting disclosure thereof in accordance with Federal Rule of Civil Procedure 26(c):

THEREFORE, it is hereby stipulated among the Parties and ORDERED that:

1. Each Party may designate as confidential for protection under this Order, in whole or in part, any document, information or material that constitutes or includes, in whole or in part, confidential or proprietary information or trade secrets of the Party or a Third Party to whom the Party reasonably believes it owes an obligation of confidentiality with respect to such document, information or material ("Protected Material"). Protected Material shall be designated by the Party producing it by affixing a legend or stamp on such document,

information or material as follows: "CONFIDENTIAL." The word "CONFIDENTIAL" shall be placed clearly on each page of the Protected Material (except deposition and hearing transcripts) for which such protection is sought. For deposition and hearing transcripts, the word "CONFIDENTIAL" shall be placed on the cover page of the transcript (if not already present on the cover page of the transcript when received from the court reporter) by each attorney receiving a copy of the transcript after that attorney receives notice of the designation of some or all of that transcript as "CONFIDENTIAL." Each page of each document produced in discovery shall, to the extent practicable, bear a prefix identifying the producing Party and a unique identifying number. Likewise, each discrete unit of tangible item produced in discovery shall, to the extent practicable, also bear a prefix identifying the producing Party and a unique identifying number.

2. Any document produced under Patent Rules 2-2, 3-2, and/or 3-4 before issuance of this Order with the designation "Confidential" or "Confidential - Outside Attorneys' Eyes Only" shall receive the same treatment as if designated "RESTRICTED - ATTORNEYS' EYES ONLY" under this Order, unless and until such document is redesignated to have a different classification under this Order.
3. With respect to documents, information or material designated "CONFIDENTIAL," or "RESTRICTED - ATTORNEYS' EYES ONLY,"<sup>1</sup> subject to the provisions herein and unless otherwise stated, this Order governs, without limitation: (a) all documents, electronically stored information, and/or things as defined by the Federal Rules of Civil Procedure; (b) all pretrial, hearing or deposition testimony, or documents marked as exhibits

---

<sup>1</sup> The term DESIGNATED MATERIAL is used throughout this Protective Order to refer to the class of materials designated as "CONFIDENTIAL," or "RESTRICTED - ATTORNEYS' EYES ONLY," both individually and collectively.

or for identification in depositions and hearings; (c) pretrial pleadings, exhibits to pleadings and other court filings; (d) affidavits; and (e) stipulations. All copies, reproductions, extracts, digests and complete or partial summaries prepared from any DESIGNATED MATERIALS shall also be considered DESIGNATED MATERIAL and treated as such under this Order.

4. A designation of Protected Material (i.e., “CONFIDENTIAL,” or “RESTRICTED - ATTORNEYS’ EYES ONLY”) may be made at any time. Inadvertent or unintentional production of documents, information or material that has not been designated as DESIGNATED MATERIAL shall not be deemed a waiver in whole or in part of a claim for confidential treatment. Any party that inadvertently or unintentionally produces Protected Material without designating it as DESIGNATED MATERIAL may request destruction of that Protected Material by notifying the recipient(s), as soon as reasonably possible after the producing Party becomes aware of the inadvertent or unintentional disclosure, and providing replacement Protected Material that is properly designated. The recipient(s) shall then destroy all copies of the inadvertently or unintentionally produced Protected Materials and any documents, information or material derived from or based thereon.
5. “CONFIDENTIAL” documents, information and material may be disclosed only to the following persons, except upon receipt of the prior written consent of the designating party, upon order of the Court, or as set forth in paragraph 13 herein:
  - (a) outside counsel of record in this Action for the Parties;
  - (b) employees of such counsel assigned to and reasonably necessary to assist such counsel in the litigation of this Action;
  - (c) in-house counsel for the Parties who either have responsibility for making decisions dealing directly with the litigation of this Action, or who are assisting outside counsel in the litigation of this Action;

- (d) up to and including three (3) designated representatives of each of the Parties to the extent reasonably necessary for the litigation of this Action, except that either party may in good faith request the other party's consent to designate one or more additional representatives, the other party shall not unreasonably withhold such consent, and the requesting party may seek leave of Court to designate such additional representative(s) if the requesting party believes the other party has unreasonably withheld such consent;
- (e) outside consultants or experts (*i.e.*, not existing employees or affiliates of a Party or an affiliate of a Party) retained for the purpose of this litigation, provided that: (1) such consultants or experts are not presently employed by the Parties hereto for purposes other than this Action<sup>2</sup>; (2) before access is given, the consultant or expert has completed the Undertaking attached as Exhibit A hereto and the same is served upon the producing Party with a current curriculum vitae of the consultant or expert at least ten (10) days before access to the Protected Material is to be given to that consultant or Undertaking to object to and notify the receiving Party in writing that it objects to disclosure of Protected Material to the consultant or expert. The Parties agree to promptly confer and use good faith to resolve any such objection. If the Parties are unable to resolve any objection, the objecting Party may file a motion with the Court within fifteen (15) days of the notice, or within such other time as the Parties may agree, seeking a protective order with respect to the proposed disclosure. The objecting Party shall have the burden of proving the need for a protective order. No disclosure shall occur until all such objections are resolved by agreement or Court order;
- (f) independent litigation support services, including persons working for or as court reporters, graphics or design services, jury or trial consulting services, and photocopy, document imaging, and database services retained by counsel and reasonably necessary to assist counsel with the litigation of this Action; and
- (g) the Court and its personnel.

6. A Party shall designate documents, information or material as "CONFIDENTIAL" only upon a good faith belief that the documents, information or material contains confidential or proprietary information or trade secrets of the Party or a Third Party to whom the Party reasonably believes it owes an obligation of confidentiality with respect to such documents,

---

<sup>2</sup> For clarity, nothing herein shall prevent a party from using an expert retained for this Action in connection with a post grant review or *inter partes* review proceeding relating to one or both of the patents-in-suit provided that the expert adheres to the requirements set forth herein.

information or material.

7. Documents, information or material produced pursuant to any discovery request in this Action, including but not limited to Protected Material designated as DESIGNATED MATERIAL, shall be used by the Parties only in the litigation of this Action and shall not be used for any other purpose; provided, however, that Defendant may use Plaintiff's DESIGNATED MATERIAL in connection with post grant review or *inter partes* review proceedings relating to one or both of the patents-in-suit so long as Defendant adheres to the terms of this protective order and any protective order filed in connection with any such post grant review or *inter partes* review proceedings.<sup>3</sup> Any person or entity who obtains access to DESIGNATED MATERIAL or the contents thereof pursuant to this Order shall not make any copies, duplicates, extracts, summaries or descriptions of such DESIGNATED MATERIAL or any portion thereof except as may be reasonably necessary in the litigation of this Action (or a post grant review or *inter partes* review proceeding directed to one or both of the patents-in-suit). Any such copies, duplicates, extracts, summaries or descriptions shall be classified DESIGNATED MATERIALS and subject to all of the terms and conditions of this Order.
8. Any individual listed in Paragraph 5(a-e) who has accessed or reviewed DESIGNATED MATERIAL (materials designated as "CONFIDENTIAL," or "RESTRICTED - ATTORNEYS' EYES ONLY") shall not participate in or aid in, directly or indirectly, the preparation or filing of any FDA Citizen Petition related to compounds, compositions,

---

<sup>3</sup> For clarity, Defendant shall comply with the terms of this protective order with respect to any Designated Material used in this Action and shall comply with terms of the protective order entered in connection with a post grant review or *inter partes* review relating to one or both of the patents-in-suit with respect to any Designated Material used in any such proceeding.

formulations, or products containing phenobarbital or phenobarbital sodium for one (1) year after the termination of this Action, including any appeals. However, this shall not preclude involvement in responding to any FDA Citizen Petition related to pharmaceutical compounds, compositions, formulations, or products containing phenobarbital or phenobarbital sodium filed by a third party to this Action with respect such Party's own product.

9. To the extent a producing Party believes that certain Protected Material qualifying to be designated CONFIDENTIAL is so sensitive that its dissemination deserves even further limitation, the producing Party may designate such Protected Material "RESTRICTED -- ATTORNEYS' EYES ONLY."
10. For Protected Material designated RESTRICTED -- ATTORNEYS' EYES ONLY, access to, and disclosure of, such Protected Material shall be limited to individuals listed in paragraphs 5(a-c) and (e-g); provided, however, that access by in-house counsel pursuant to paragraph 5(c) be limited to in-house counsel who exercise no competitive decision-making authority on behalf of the client and who is bound by paragraph 11.
11. Any attorney representing a Party, whether in-house or outside counsel, and any person associated with a Party and permitted to receive the other Party's DESIGNATED MATERIAL (materials designated as "CONFIDENTIAL," or "RESTRICTED - ATTORNEYS' EYES ONLY"), who obtains, receives, has access to, or otherwise learns, in whole or in part, the other Party's DESIGNATED MATERIAL under this Order shall not directly or indirectly prepare, prosecute, supervise, or assist in the preparation or prosecution of any patent application pertaining to the field of the invention of the patents-in-suit on behalf of the receiving Party or its acquirer, successor, predecessor, or other

affiliate during the pendency of this Action and for two years after its conclusion, including any appeals. To ensure compliance with the purpose of this provision, each Party shall create an “Ethical Wall” between those persons with access to DESIGNATED MATERIAL and any individuals who, on behalf of the Party or its acquirer, successor, predecessor, or other affiliate, prepare, prosecute, supervise or assist in the preparation or prosecution of any patent application pertaining to the field of invention of the patent-in-suit. Notwithstanding the foregoing, nothing herein shall preclude individuals listed in Paragraph 5(a-e) from working on and participating in, directly or indirectly, (i) all aspects of any *inter partes* review, post-grant review, or re-issue or re-examination proceeding at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board concerning the patents-in-suit, except for claim drafting, and (ii) all aspects of any pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court for a patent or patent application except for claim drafting. To avoid any misunderstanding, and consistent with the scope of the foregoing terms, nothing herein shall preclude the individuals listed in Paragraph 5(a-e) from engaging in supervisory roles in patent prosecution concerning the field of the invention of the patents-in-suit that do not involve drafting, amending, or providing instruction with respect to the drafting or amending of claims, or being involved in proceedings or litigations relating to patent term extension under 35 U.S.C. § 156 *et seq.* or patent term adjustment under 35 U.S.C. § 154 *et seq.* for a patent or patent application concerning the field of the invention of the patents-in-suit.

12. Nothing in this Order shall prejudice the right of any party to oppose production of any information for lack of relevance. Nonetheless, information in a document may be redacted on the basis of relevance only to the extent such information concerns another product that

is not at issue in this Action. Redactions on this basis shall identify where such information was redacted and shall include a “Prod” or “Product” label.

13. Nothing in this Order shall require production of documents, information or other material that a Party contends is protected from disclosure by the attorney-client privilege, the work product doctrine, or other privilege, doctrine, or immunity. If documents, information or other material subject to a claim of attorney-client privilege, work product doctrine, or other privilege, doctrine, or immunity is inadvertently or unintentionally produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any such privilege, doctrine, or immunity. Any Party that inadvertently or unintentionally produces documents, information or other material it reasonably believes are protected under the attorney-client privilege, work product doctrine, or other privilege, doctrine, or immunity may obtain the return of such documents, information or other material by promptly notifying the recipient(s) and providing a privilege log for the inadvertently or unintentionally produced documents, information or other material. The recipient(s) shall gather and return all copies of such documents, information or other material to the producing Party, except for any pages containing privileged or otherwise protected markings by the recipient(s), which pages shall instead be destroyed and certified as such to the producing Party.
14. There shall be no disclosure of any DESIGNATED MATERIAL by any person authorized to have access thereto to any person who is not authorized for such access under this Order. The Parties are hereby ORDERED to safeguard all such documents, information and material to protect against disclosure to any unauthorized persons or entities.
15. Nothing contained herein shall be construed to prejudice any Party’s right to use any

DESIGNATED MATERIAL in taking testimony at any deposition or hearing provided that the DESIGNATED MATERIAL is only disclosed to a person(s) who is: (i) eligible to have access to the DESIGNATED MATERIAL by virtue of his or her employment with the designating party, (ii) identified in the DESIGNATED MATERIAL as an author, addressee, or copy recipient of such information, (iii) although not identified as an author, addressee, or copy recipient of such DESIGNATED MATERIAL, has, in the ordinary course of business, seen such DESIGNATED MATERIAL, (iv) a current or former officer, director or employee of the producing Party or a current or former officer, director or employee of a company affiliated with the producing Party; (v) counsel for a Party, including outside counsel and in-house counsel (subject to paragraph 10 of this Order); (vi) an independent contractor, consultant, and/or expert retained for the purpose of this litigation; (vii) court reporters and videographers; (viii) the Court; or (ix) other persons entitled hereunder to access to DESIGNATED MATERIAL. DESIGNATED MATERIAL shall not be disclosed to any other persons unless prior authorization is obtained from counsel representing the producing Party or from the Court.

16. Parties may, at the deposition or hearing or within thirty (30) days after receipt of a deposition or hearing transcript, designate the deposition or hearing transcript or any portion thereof as “CONFIDENTIAL” or “RESTRICTED - ATTORNEY’ EYES ONLY” pursuant to this Order. Access to the deposition or hearing transcript so designated shall be limited in accordance with the terms of this Order. Until expiration of the 30-day period, the entire deposition or hearing transcript shall be treated as “RESTRICTED - ATTORNEY’ EYES ONLY”.
17. Any DESIGNATED MATERIAL that is filed with the Court shall be filed under seal and

shall remain under seal until further order of the Court. The filing party shall be responsible for informing the Clerk of the Court that the filing should be sealed and for placing the legend “FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER” above the caption and conspicuously on each page of the filing. Exhibits to a filing shall conform to the labeling requirements set forth in this Order. If a pretrial pleading filed with the Court, or an exhibit thereto, discloses or relies on confidential documents, information or material, such confidential portions shall be redacted to the extent necessary and the pleading or exhibit filed publicly with the Court.

18. The Order applies to pretrial discovery. Nothing in this Order shall be deemed to prevent the Parties from introducing any DESIGNATED MATERIAL into evidence at the trial of this Action, or from using any information contained in DESIGNATED MATERIAL at the trial of this Action, subject to any pretrial order issued by this Court.
19. A Party may request in writing to the other Party that the designation given to any DESIGNATED MATERIAL be modified or withdrawn. If the designating Party does not agree to redesignation within ten (10) days of receipt of the written request, the requesting Party may apply to the Court for relief. Upon any such application to the Court, the burden shall be on the designating Party to show why its classification is proper. Such application shall be treated procedurally as a motion to compel pursuant to Federal Rules of Civil Procedure 37, subject to the Rule’s provisions relating to sanctions. In making such application, the requirements of the Federal Rules of Civil Procedure and the Local Rules of the Court shall be met. Pending the Court’s determination of the application, the designation of the designating Party shall be maintained.
20. Each outside consultant or expert to whom DESIGNATED MATERIAL is disclosed in

accordance with the terms of this Order shall be advised by counsel of the terms of this Order, shall be informed that he or she is subject to the terms and conditions of this Order, and shall sign an acknowledgment that he or she has received a copy of, has read, and has agreed to be bound by this Order. A copy of the acknowledgment form is attached as Appendix A. Discovery of communications between counsel and any outside consultant or expert retained or specially employed by that counsel shall be limited to factual information, analyses, documents, and data relied on by the expert in rendering the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all other communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working papers, notes, and communications relating thereto, shall be deemed exempt from discovery and use at trial.

21. To the extent that any discovery is taken of persons who are not Parties to this Action (“Third Parties”) and in the event that such Third Parties contend the discovery sought involves trade secrets, confidential business information, or other proprietary information, then such Third Parties may agree to be bound by this Order.
22. To the extent that discovery or testimony is taken of Third Parties, the Third Parties may designate as “CONFIDENTIAL” or “RESTRICTED -- ATTORNEYS’ EYES ONLY” any documents, information or other material, in whole or in part, produced or given by such Third Parties. The Third Parties shall have ten (10) days after production of such documents, information or other materials to make such a designation. Until that time period lapses or until such a designation has been made, whichever occurs sooner, all documents, information or other material so produced or given shall be treated as

“CONFIDENTIAL” in accordance with this Order.

23. If any third party requests the production of any DESIGNATED MATERIAL, including, but not limited to, a request by subpoena, the receiving Party in possession of such DESIGNATED MATERIAL must (a) notify the producing Party within seven (7) business days of receiving the request; and (b) permit the producing Party a reasonable opportunity to intervene and be heard.
24. Within thirty (30) days of final termination of this Action, including any appeals, all DESIGNATED MATERIAL, including all copies, duplicates, abstracts, indexes, summaries, descriptions, and excerpts or extracts thereof (excluding excerpts or extracts incorporated into any privileged memoranda of the Parties and materials which have been admitted into evidence in this Action), shall at the producing Party’s election either be returned to the producing Party or be destroyed. The receiving Party shall verify the return or destruction by affidavit furnished to the producing Party, upon the producing Party’s request.
25. The failure to designate documents, information or material in accordance with this Order and the failure to object to a designation at a given time shall not preclude the filing of a motion at a later date seeking to impose such designation or challenging the propriety thereof. The entry of this Order and/or the production of documents, information and material hereunder shall in no way constitute a waiver of any objection to the furnishing thereof, all such objections being hereby preserved.
26. Any Party knowing or believing that any other party is in violation of or intends to violate this Order and has raised the question of violation or potential violation with the opposing party and has been unable to resolve the matter by agreement may move the Court for such relief as may be appropriate in the circumstances. Pending disposition of the motion by the

Court, the Party alleged to be in violation of or intending to violate this Order shall discontinue the performance of and/or shall not undertake the further performance of any action alleged to constitute a violation of this Order.

27. Production of DESIGNATED MATERIAL by each of the Parties shall not be deemed a publication of the documents, information and material (or the contents thereof) produced so as to void or make voidable whatever claim the Parties may have as to the proprietary and confidential nature of the documents, information or other material or its contents.
28. Nothing in this Order shall be construed to effect an abrogation, waiver or limitation of any kind on the rights of each of the Parties to assert any applicable discovery or trial privilege. Notwithstanding the foregoing provisions, this Order shall be without prejudice to the right of any party to challenge the propriety of discovery on grounds of privilege, relevance, and/or materiality, and nothing contained herein shall be construed as a waiver of any objection that might be raised as to the admissibility at trial of any evidentiary material. This Order is being entered without prejudice to the right of any party to move the Court for modification or for relief from any of its terms.
29. Each of the Parties shall also retain the right to file a motion with the Court (a) to modify this Order to allow disclosure of DESIGNATED MATERIAL to additional persons or entities if reasonably necessary to prepare and present this Action and (b) to apply for additional protection of DESIGNATED MATERIAL.

**SIGNED this 2nd day of October, 2024.**



\_\_\_\_\_  
ROY S. PAYNE  
UNITED STATES MAGISTRATE JUDGE

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

NIVAGEN, INC.,

Plaintiff

v.

SUN PHARMACEUTICALS INDUSTRIES,  
INC., SUN PHARMACEUTICAL INDUSTRIES  
LTD., SUN PHARMA ADVANCED RESEARCH  
COMPANY LTD., SUN PHARMACEUTICAL  
MEDICARE LTD.,

Defendants.

Case No.: 2:24-cv-00036-RWS-RSP

**APPENDIX A  
UNDERTAKING OF EXPERTS OR CONSULTANTS REGARDING  
PROTECTIVE ORDER**

I, \_\_\_\_\_, declare that:

1. My address is \_\_\_\_\_  
My current employer is \_\_\_\_\_  
My current occupation is \_\_\_\_\_
2. I have received a copy of the Protective Order in this action. I have carefully read and understand the provisions of the Protective Order.
3. I will comply with all of the provisions of the Protective Order. I will hold in confidence, will not disclose to anyone not qualified under the Protective Order, and will use only for purposes detailed in Paragraph 7 of the Protective Order any information designated as  
"CONFIDENTIAL," or "RESTRICTED -- ATTORNEYS' EYES ONLY" that is disclosed to me.
4. Promptly upon termination of these actions, I will return all documents and things

designated as "CONFIDENTIAL," or "RESTRICTED -- ATTORNEYS' EYES ONLY" that came into my possession, and all documents and things that I have prepared relating thereto, to the outside counsel for the party by whom I am employed as detailed in Paragraph 24 of the Protective Order.

5. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order in this action.

I declare under penalty of perjury that the foregoing is true and correct.

Signature \_\_\_\_\_

Date \_\_\_\_\_

**ATTACHMENT B**

**CERTIFICATE OF AUTHENTICITY OF BUSINESS RECORDS**

I, the undersigned, \_\_\_\_\_ with the understanding that I am  
Name  
subject to criminal penalty under the laws of the United Kingdom for an intentionally false  
declaration, declare that I am employed as \_\_\_\_\_ with  
Position  
Pharmanovia, and by reason of my position am authorized and qualified to make this declaration.

I further declare that to the best of my knowledge and belief the documents provided to  
the judicial authority for onwards transmission to the United States District Court for the Eastern  
District of Texas, pursuant to the letter of request served on said judicial authority, are original  
records or true copies of records which:

1. Were made at or near the time of the occurrence of the matters set forth therein, by (or  
from information transmitted by) a person with knowledge of those matters;
2. Were kept in the course of a regularly conducted business activity;
3. Were made by the said business activity as a regular practice; and
4. If not original records, are duplicates of original records.

The original or duplicates of these records were/are maintained in \_\_\_\_\_.  
Location

---

Date of execution

---

Signature

---

Place of execution

---

Witnessed